WWW.IJRPR.COM

International Journal of Research Publication and Reviews

Journal homepage: www.ijrpr.com ISSN 2582-7421

Development and Evaluation of Mouth Dissolving Films Using Chitosan, Guar Gum and Sodium Alginate Polymers

Yuvraj Batish[1],Monika Bansal[2], Babaldeep Kaur[3]

Akal College of Pharmacy & Technical Education, Mastuana Sahib, Sangrur, India – 148 001
Corresponding author:
Mrs. Monika Bansal; Associate Professor
E mail: monikabansal8@gmail.com

ABSTRACT:

The research focused on the development and assessment of oral dissolving films (ODFs) utilizing chitosan, guar gum, and sodium alginate as individual polymers via the solvent casting method. Various concentrations of these polymers were employed in film preparation. The evaluation parameters encompassed thickness test, weight variation test, tensile strength, percentage elongation, folding endurance, swelling index, Disintegration test, compound microscopy, percentage moisture uptake and loss, surface pH, and organoleptic tests (colour, odour, and surface morphology). The study successfully formulated oral dissolving films using chitosan, guar gum, and sodium alginate, with each formulation meeting the predetermined evaluation criteria. Results were meticulously recorded in tabular format, facilitating clear comparison and analysis.

For formulations that did not meet the desired standards, the reasons for failure were discussed within the article's discourse. Additionally, proposed improvements and modifications were elucidated to address deficiencies and enhance film properties. The article comprehensively delineated the step-by-step process of preparing successful oral dissolving films, providing valuable insights into the formulation and evaluation methodology. Overall, the research contributes to the advancement of pharmaceutical film technology and offers potential applications in oral drug delivery systems.

INTRODUCTION:

1. **Mouth dissolving films:** A drug can be administered via many different routes to produce a systemic pharmacologic effect. The most common method of drug administration is via the Peroral route, in which the drug is swallowed and enters the systemic circulation primarily through the membranes of the small intestine. Although this type of drug administration is commonly termed oral. Peroral is a better term because oral administration more accurately describes drug absorption from the mouth itself. In general, mucosal DDS drugs penetrate the mucous membrane by simple diffusion and are carried in the blood, which richly supplies the salivary glands and their ducts, into the systemic circulation via the jugular vein. Mucosal drug delivery has lately become an important route of drug administration (Chaturvedi, Srivastava et al. 2011).

2. Classification of Orodispersible Films (ODFs)

ODFs are typically categorized into three classes based on their dissolution characteristics, layering structure, and the nature of the active pharmaceutical ingredient (API).

1. Type 1 ODFs: Classification by Dissolution

Type 1 ODFs are further divided into three subclasses based on their dissolution time: fast, moderate, and slow.

- Fast-dissolving ODFs dissolve within 30 seconds and have a thickness of approximately 50–150 μm. They are often used in emergency situations.
- Moderately dissolving ODFs dissolve within 1–30 minutes and are suitable for applications requiring gradual release.
- Slow-dissolving ODFs take over 30 minutes to dissolve and are commonly utilized for nicotine-based products, aiding in reducing cravings in individuals dependent on tobacco (Cazón, 2020).

2. Type 2 ODFs: Classification by Layering

Type 2 ODFs are categorized by the number of layers they contain:

- Monolayer films consist of a single layer comprising the API, a film-forming polymer, and excipients.

- Bilayer or double-layer films include one layer containing the API and another layer designed for taste masking or permeation enhancement.
- Multilayer films sandwich the API layer between two additional layers, providing added functionality or protection.

3. Type 3 ODFs: Classification by API Source

Type 3 ODFs are classified based on the origin of the API:

- Synthetic APIs such as sildenafil.
- Natural APIs derived from plants or animals, such as ginger or turmeric.
- Films containing minerals, vitamins, vaccines, or micronutrients, like vitamin D ODFs, also fall under this category.

These films may incorporate either prescription or over-the-counter drugs. However, ODFs using plant-based APIs are challenging to fabricate (Priya, 2024).

3. Packaging of Oral dissolving film

Preserving the quality of pharmaceutical products is essential in the industry, necessitating careful selection of packaging. This involves specific manufacturing and storage procedures, particularly for fast-dissolving dosage forms. While various packaging options exist for such films, single-use aluminium pouches are commonly used. APR-Labtech has introduced the Rapid card, a proprietary packaging system tailored for their Rapid films. Resembling a credit card, it accommodates three films on each side, enabling individual dosing

The material chosen must possess the following attributes:

- Ensures protection of the product from environmental influences.
- Holds FDA approval.
- Meets tamper-resistant standards as required.
- Is non-toxic and non-reactive with the product.
- Does not introduce any taste or odour to the product (Khalid, 2021)

4. Types of packaging of oral dissolving film

1)Single pouch and Aluminium pouch

The peelable pouch for soluble film drug delivery dissolves quickly and boasts high barrier properties. It's transparent for product visibility and utilizes a two-structure combination, with one side clear and the other using cost-effective foil lamination. This lamination effectively blocks gas and moisture transmission. The pouch offers a thin, flexible film option for nutraceutical and pharmaceutical use, providing protection for both product and dosage. Aluminium pouches are commonly employed for this purpose

2) Foil, paper or plastic pouches

The flexible pouch is versatile, providing both tamper resistance and environmental protection through material selection. It's formed during product filling using vertical or horizontal equipment and can be made of foil, paper, or plastic.

3) Blister card with multiple units

On the other hand, blister cards consist of a blister, which holds the product, and a lid stock that seals it. Film selection depends on the required level of protection, with aluminium foil commonly used for the lid stock. The cavity material is usually plastic and can be designed to protect the dosage form from moisture

4) High barrier films

They are essential for drug preparations sensitive to moisture, with materials like polychlorotrifluoroethylene film and polypropylene commonly used to provide moisture protection

5) Continuous roll dispensers

an automatic device dispenses and measures drug tape from a disposable cassette housed in a portable dispenser. It includes a measurement device to accurately dispense tape length, a counter to monitor remaining doses, and a timer to remind patients of dosing times. When opened, the dispenser cuts a measured length of drug tape for each dose, allowing for precise dosage administration (Wasilewiska et al., 2019).

5. Applications of oral dissolving film

1. Topical applications: Dissolvable films could potentially be used to administer active ingredients like painkillers or antimicrobial agents for treating wounds and various other applications (Kumar, Yagnesh et al. 2019)
2. Gastro retentive dosage systems: The use of soluble films in dosage forms that comprise compounds with varying molecular weights that are soluble in water and weakly soluble in other solvents is being explored for gastro-retentive dosing systems. Treatment for gastrointestinal diseases may involve using the films, which may dissolve due to the pH or the digestive tract's secretions of enzymes (Pawar, Sharma et al. 2019)

3. Diagnostic devices: Biological fluids can trigger a controlled release of reagents from dissolvable films that are filled with sensitive reagents. Alternatively, numerous reagents can be separated by isolation barriers to facilitate a timed reaction within the diagnostic device (Patel, Prajapati et al. 2023).
4. Vaccines: Vaccinations that readily dissolve in saliva and the mouth can be administered using fast dissolving buccal films. These vaccinations are stable at room temperature. Almost as easy to administer as mouthwash, the US-made rotavirus vaccine is a buccal film that dissolves quickly and is stable at room temperature. This delivery approach has several advantages, including better patient compliance, higher bioavailability, and lower handling, administration, and storage costs (Pattewar, Kasture et al. 2016).
5. Controlled and sustained release film Hospitals use chitin and chitosan derivatives as excipients while preparing patients for sustained-release buccal films, among other types of polymers (Kushwaha, Akhtar et al. 2015).
6. Taste masking: To be successful on the market, fast dissolving tablets need to contain taste masking. Fast-dissolving buccal films dissolve or break down in the patient's mouth, releasing the active substances that come into touch with the taste buds. Therefore, for the patient to be able to comply with this quality it is essential. Medicinal products with an unfavourable bitter taste can be microencapsulated into acrylic polymer by solvent evaporation and solvent extraction (Gupta, Mishra et al. 2010).

General Method of Preparation

Steps for preparing oral dissolving films using the solvent casting method:

1. Selection of Ingredients: Different potential film-forming polymers were selected such as chitosan, guar gum and sodium alginate, along with other excipients like plasticizers, flavors, and sweeteners. The selected polymers are high-performance solids that form strong, adherent films which are widely used across various industries, including cosmetics, pharmaceuticals, and surface coatings. Moreover, the polymers were selected considering different chemical groups in their structure.
2. Preparation of Polymer Solution: Film manufacturing was carried out using solvent casting methods as previously described. In summary, an aqueous film solution containing the excipients was prepared. The selected polymers were dissolved in distilled water with mild heating, if required in certain batches with continuous stirring to form a homogenous mixture. The stirring was done slowly so that no bubbles were formed and trapped in between the mixture. After the preparation of homogenous mixture, the mixture was subjected to ultrasonication so as to remove foam from the mixture. Table represents the combination of different formulation trials with different potential polymers with varying concentrations polymer and excipients so as to evaluate the effect of different polymers and different concentrations on the quality of polymeric film.
3. Addition of Excipients: In a homogenous mixture of polymer dispersion glycerol and propylene glycol were added slowly with continuous stirring. Addition of plasticizers is necessary in order enhance the flexibility and durability of the film. Further, flavours and sweeteners were added with continuous stirring to improve palatability.
4. Homogenization: Final dispersion was subjected to homogenization so as to ensure uniform dispersion of all ingredients.
5. Degassing: Optionally, the final dispersion was subjected to ultrasonication so as to degas the solution and remove any entrapped air bubbles and foam, which can lead to defects in the final film such as drug content non-uniformity.
6. Casting: Pour the prepared solution onto a flat, clean surface such as a glass plate or a stainless steel mould. Spread the solution evenly using a suitable tool like a film applicator or a spreader bar to achieve the desired thickness. In this process it is important to maintain the thickness of the film. Therefore, to ensure the thickness same glass plate was used to develop films and same volume of polymeric dispersions were added in the glass plate.
7. Drying: The cast films were allowed to dry at room temperature or under controlled conditions, such as in an oven or a desiccator, to remove the solvent. This process may take several hours to overnight, depending on the thickness of the film and drying conditions**.** High temperature and excessive exposure to heating must be avoided while drying as it may degrade the polymeric film and brittleness may be seen in the final formulation.

Table: Different formulation trials with different potential polymers with varying concentrations polymer and excipients.

S.NO	Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	Chitosan (mg)	100	500	1000	-	-	-	-	-	-
2	Guar Gum (mg)	-	-	-	400	450	500	-	-	-
3	Sodium Alginate (mg)	-	-	-	-	-	-	200	300	400
4	Acetic acid (%v/v)	2	2	2	-	-	-	-	-	-
5	Glycerol (ml)	10	5	2	10	5	2	10	5	2
6	Tween 80 (ml)	1	0.5	0.5	1	0.5	0.5	1	0.5	0.5
7	Mannitol (mg)	10	10	10	10	10	10	10	10	10
8	Citric Acid (mg)	-	-	-	10	10	10	10	10	10
9	Distilled Water (ml)	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s

Characterization of the films:

Organoleptic tests

The desired organoleptic properties for a fast-dissolving formulation include color, flavor, taste, surface morphology, and film coming ability. As these formulations are intended to rapidly disintegrate in the oral cavity, they must exhibit acceptable sensory characteristics. Uniform and attractive coloration enhances the formulation's acceptability, especially among pediatric patients, and can be assessed visually. Pleasant odor is achieved through the use of flavoring agents to mask any unpleasant smells from the polymer, drug, or other excipients.Surface morphology, which refers to the physical structure of the formulation's surface, is crucial for ensuring efficacy and patient satisfaction.

Film forming ability refers to the capacity of a substance to rapidly and effectively transform into a thin, cohesive film when exposed to a suitable medium such as saliva or an aqueous solution.This ability is crucial in thin films where the rapid disintegration and dissolution of the film are desired for efficient drug delivery.

Thickness of the film:

Vernier calipers are used to measure the thickness of the film. Thickness is measured at five spots: the center and four corners. The measurements are added up and divided by five to find the average thickness. The thickness should be between 5 and 200 units. Samples with air bubbles, nicks, tears, or more than a 5% variation in mean thickness are not suitable for analysis. Ensuring consistent thickness throughout the film is crucial as it directly affects the accuracy of dose distribution.

(1) Least count of vernier caliper (vc)=The value of one division on vernier scale/total no. of division on vernier scale =1/10mm or 0.1mm

(2) zero error=0

(3) for thickness of the film

Surface pH test:

It's important to assess the surface pH of fast dissolving strips as it can affect the oral mucosa. The ideal surface pH for these films is around 7, close to neutral. A combined pH electrode is used to measure the surface pH. The electrode is brought into contact with the slightly wet oral film to measure the pH with water. This study involves testing at least six films of each formulation, and their mean ± standard deviation (SD) can be calculated.

Folding endurance

To find folding endurance, a strip of film is repeatedly folded at the same spot until it breaks. The number of times it can be folded without breaking indicates its folding endurance, which reflects the film's brittleness. The method involves folding a 2x2 cm film specimen repeatedly at the same spot until it breaks or shows a visible crack. The folding endurance value is the number of times it can be folded without breaking or showing any visible cracks.

Weight variation test:

In the test, three 2x2 cm film strips are cut from different areas of the cast film. The weight of each strip is measured, and any variations in weight are noted.

WEIGHT VARIATION = IW-AW/AW*100%

Where,

IW= Individual weight

AW=Average weight

Percent elongation

Percent elongation is a measure of how much a film stretches before breaking when sufficient force is applied to exceed its elastic limit.

The original length of the film is measured and tension is applied to it until it breaks.

The length is measured at which it breaks and change in length of sample is calculated by:

Change in length=final length - original length

Then, percent elongation is calculated using the equation:

% Elongation = (Increase in length at breaking point / original length) × 100.

When stress is applied to a 2 × 2 cm film sample, it undergoes strain, which is the deformation of the strip before breaking due to stress. Generally, the elongation of the strip increases as the plasticizer content increases.

Disintegration time

The disintegration time of a dissolvable film is the moment it begins to break down upon contact with water or saliva, typically lasting between seconds to a few minutes for oral dissolving films. The disintegration test is conducted using a Disintegration apparatus as per the United States Pharmacopoeia (USP) standards. Alternatively, the disintegration time can be visually observed by immersing the film in 25 ml of water in a beaker, gently shaking it, and noting the time when the film starts to break or disintegrate.

Percentage moisture loss

Percent moisture loss is a parameter that determines the hygroscopicity of a film. Usually, this parameter is determined by first finding the initial weight of the film, afterward, putting this film in a desiccator for three days. Desiccator contains calcium carbonate. After three days, strips are taken out and weighed again. Moisture loss is determined by applying the following formula

To determine the percentage of moisture loss, films with dimensions of 2 × 2 cm are accurately weighed on an electronic balance. These films are then placed in desiccators containing fused anhydrous calcium chloride and left for 72 hours. After this period, the films are removed, reweighed, and the percentage of moisture loss is calculated using the formula:
Percent moisture loss = ((Initial weight - Final weight) / Initial weight) × 100. These studies are conducted to assess the physical stability and integrity of the film.

Moisture uptake
Moisture uptake of a film is determined by first cutting the film with the dimension of 2 × 2 cm2. Afterward these strips are exposed to environment with a relative humidity of 75% at room temperature for 7 days. Moisture uptake is determined as percent weight gain of the strips.
Percentage moisture uptake = final weight - initial weight/initial weight × 100

Results and Discussion

Organoleptic properties of the films:

These properties include the visual appeal, taste, odor, and texture of the film, which collectively influence the overall patient experience. A well-designed ODF should have an appealing appearance, a pleasant or neutral taste, an agreeable odor, and a smooth texture to ensure ease of administration and patient comfort.
Taste masking is particularly important for ODFs, as the rapid dissolution of the film in the oral cavity exposes the drug immediately to taste receptors. Bitter or unpleasant tastes must be masked using flavoring agents, sweeteners, or encapsulation techniques. Similarly, odors from active pharmaceutical ingredients or excipients can be neutralized or masked with suitable aromatic agents. The film's texture should be non-gritty and uniform to avoid discomfort during administration, which could otherwise lead to patient dissatisfaction (Guo et al., 2020).
In addition to these sensory attributes, the visual appeal of ODFs, including color and transparency, can also influence user acceptance. Bright, uniform colors and clear labeling enhance the product's appeal while ensuring ease of identification. Overall, optimizing the organoleptic properties of ODFs is essential for enhancing patient adherence, particularly for formulations targeting populations with higher sensitivity to sensory experiences.

Table 15: Observation table for organoleptic properties Oral Dissolving film (ODF)

	Chitosan ODF	**Guar Gum ODF**	**Sodium Alginate ODF**
Colour	Transparent	Translucent	Yellowish brown
Odour	Odourless	Odourless	Odourless
Film Forming ability	Excellent	Very Good	Very good
Surface Morphology	Smooth	Smooth	Smooth

Evaluation of film thickness: Film thickness and appearance were recorded for all the developed batches. The thickness of thin films is a critical parameter, as it significantly influences many of the film's properties. Moreover, measuring film thickness is essential in various sectors of the pharmaceutical industry because it directly affects drug content uniformity. This study aims to ensure that all batches with the same formulation maintain uniform thickness, thereby validating consistency in both quality parameters and process parameters (Maciel et al., 2021).

Table 5: Observation table for thickness observed in the polymeric films formed by chitosan

SNO.	**MAIN SCALE (MC) READING (in mm)**	**NO. OF DIVISIONS IN VERNIER SCALE (VC)**	**VFFS READING (NO. OF DIVISIONS * LC OF VS)**	**TOTAL READING (MS+VS) (in mm)**
F1	0.2	2	1*0.1=0.2	0.4
F2	0.2	3	2*0.1=0.3	0.5
F3	0.2	3	1*0.1=0.3	0.5
			Average	0.47 mm

Calculation:

$$Average\ thickness = \left(\frac{0.4 + 0.5 + 0.5}{3}\right) mm$$

The average thickness for all the batched developed form chitosan was calculated as 0.47 ± 0.03 mm. The low value of standard deviation ensures the consistency in the thickness between different batches. Moreover, thickness was observed to be less than 0.5 mm which further ensures the potential film for orodispersible purpose as per literature. In several literature, the optimum thickness for various orodispersible polymeric films was observed to be less than 0.5 mm which further confirms the developed films are ideal candidate for orodispersible films.

Table 6: Observation table for thickness observed in the polymeric films formed by guar gum

SNO.	MAIN SCALE (MC) READING (in mm)	NO. OF DIVISION IN VERNIER SCALE (VC)	VS READING (NO. OF DIVISION * LC OF VS)	TOTAL READING (MS+VS) (in mm)
F4	0.1	2	0.2	0.3
F5	0.1	1	0.1	0.2
F6	0.1	2	0.2	0.3
			Average	0.27 mm

Calculation:

$$Average\ thickness = \left(\frac{0.3 + 0.2 + 0.3}{3}\right) mm$$

The average thickness for all the batched developed form guar gum was calculated as 0.27 ± 0.04 mm. The low value of standard deviation ensures the consistency in the thickness between different batches. Moreover, thickness was observed to be less than 0.5 mm which further ensures the potential film for orodispersible purpose as per literature. Further, in comparison to polymeric films prepared by chitosan the thickness was observed to be somewhat less in thickness. In several literature, the optimum thickness for various orodispersible polymeric films was observed to be less than 0.5 mm which further confirms the developed films are ideal candidate for orodispersible films.

Table 7: Observation table for thickness observed in the polymeric films formed by sodium alginate

SNO.	MAIN SCALE (MC) READING (in mm)	NO. OF DIVISION IN VERNIER SCALE (VC)	VS READING (NO. OF DIVISION * LC OF VS)	TOTAL READING (MS+VS) (in mm)
F7	0.1	1	0.1	0.2
F8	0.1	1	0.1	0.2
F9	0.1	1	0.1	0.2
			Average	0.2 mm

Calculation:

$$Average\ thickness = \left(\frac{0.2 + 0.2 + 0.2}{3}\right) mm$$

The average thickness for all the batched developed form guar gum was calculated as 0.2 ± 0.00 mm. The low value of standard deviation ensures the consistency in the thickness between different batches. Moreover, thickness was observed to be less than 0.5 mm which further ensures the potential film for orodispersible purpose as per literature. Further, in comparison to polymeric films prepared by chitosan and guar gum, the thickness was observed to be somewhat very less in thickness and more consistent. In several literature, the optimum thickness for various orodispersible polymeric films was observed to be less than 0.5 mm which further confirms the developed films are ideal candidate for orodispersible films. Although, the thickness observed was too less as compared to films prepared by chitosan and guar gum which signifies better orodispersible film but there are certain drawbacks associated with very thin films i.e. low endurance and poor mechanical properties which may have impact in stability particularly associated with packaging, storage and transport. Hence, the developed films were further subjected to evaluation of film endurance so as to shortlist the better films for intended use.

Selected formulations:

1. **For chitosan film: F3** formulation was selected amongst the three formulations made.

The reasons for failure of F1 formulation can be:

1) Polymer concentration taken was insufficient to make a proper film. Due to low concentration of polymer the film was not able to dry even after specified heating for specific time period.

2)The polymer was not completely soluble in distilled water. Absence of acetic acid solution could be the reason for this.

Reasons behind failure of F2 formulation

1) Film was heated at high temperatures due to which film cracked and brown edges were observed in film.

2) Magnetic Stirrer was used for dissolving the polymer which was proved out to be ineffective because polymer was not completely dissolved.

2. **Guar Gum Film : F6** formulation was chosen as F4 and F5 could not make good films.

Reasons behind failure of F4 formulation

The polymer was not dissolved properly and the film has lumps in it due to which the film formed is not transparent, thicker than natural and has uneven slippery surface. There are two reasons behind it. These are :-

- The polymer was not completely dissolved in distilled water which is evident with the formation of lumps in the mixture. The methods employed to combat this problem are :-
    - The polymer solution was mixed manually with glass rod by gradual addition of ice cold water.
    - Then taken this solution in test tube and stirred it at 1000 rpm for half an hour.
    - At last this solution was heated on heating mantle at 40-50℃ for half an hour and slowly breaking the lumps with glass rod and constant stirring.
- The film formed is slippery in nature due to addition of plasticizer in somewhat larger amount which lead to the formation of slippery film.

Reasons behind failure of F5 formulation

- The film formed had bubbles in it which decrease the overall appearance of film. This problem arise because of insufficient sonication of the film solution and the resting time of the polymer solution is also low. The method employed to overcome this problem are-:
    - The polymer solution was allowed to rest for 18-20 hours in a beaker packed with paper from top. This automatically decreased the bubbles present in solution and also the guar gum was completely dissolved without any lumps in it.
    - The sonication time was increased from 30 minutes to 45-50 minutes which completely removed the bubbles.

2. **Sodium Alginate Film: F9 formulation was selected amongst F7, F8 and F9.**

Reasons behind failure of F7 formulation

- The polymer concentration taken was not sufficient to form a film. Therefore the film solution was not able to dry even after 24 hours of drying under sunlight.

Reasons behind failure of F8 formulation

- The film was dried on high temperature due to which the film formed was dark rough and thick.
- The film was not poured properly on petri plate due to which the film had cracks in it.

Hence, further characterization studies were performed on the **F3, F6 and F9** for chitosan, guar gum and sodium alginate respectively.

pH of the prepared films: The pH of buccal films influences their stability, drug release, and compatibility with the buccal mucosa. Buccal films are designed to deliver drugs directly through the mucosal tissues, which typically have a pH range of 5.5 to 7.4. To ensure optimal performance and minimize irritation, the pH of the film should ideally be within this range. A compatible pH ensures better drug absorption and reduces the risk of mucosal irritation or damage. Moreover, the pH can affect the solubility and ionization state of the drug, influencing its bioavailability (Morales et al., 2011).

Table 14: Observation table for pH test

SELECTED FORMULATIONS	Batches made						Average
	B1	**B2**	**B3**	**B4**	**B5**	**B6**	
CHITOSAN (F3)	6.18	6.24	6.52	6.44	6.17	6.60	**6.35**
GUAR GUM (F6)	6.56	6.48	6.61	6.78	6.53	6.89	**6.64**
SODIUM ALGINATE (F9)	6.86	6.90	6.88	6.62	6.58	6.44	**6.71**

Evaluation of Folding endurance:

Folding endurance is a critical parameter in evaluating the mechanical properties of buccal films. It reflects the film's flexibility, durability, and resistance to mechanical stress during handling and application. The test involves repeatedly folding the film at the same point until it breaks or shows visible signs of cracking. A high folding endurance indicates a robust and flexible film capable of withstanding repeated folding without losing its integrity. This property is essential for ensuring the film's stability and usability in real-world applications (Nagaraju et al., 2013).

Table 8: Observation table for folding endurance

SELECTED FORMULATIONS	BATCHES MADE						AVERAGE
	B1	**B2**	**B3**	**B4**	**B5**	**B6**	
CHITOSAN (F3)	69	71	62	84	78	75	**73**
GUAR GUM (F6)	250	244	257	229	267	289	**256**
SODIUM ALGINATE (F9)	117	120	109	133	128	123	**122**

Folding endurance values typically range from 50 to 300 folds, depending on the formulation and intended use of the buccal film. A high folding endurance (e.g., >200 folds) is desirable for films designed for prolonged application, as it ensures the film remains intact during use. Low folding endurance may indicate brittleness or poor formulation and could lead to film breakage during handling or application (Pacheco et al., 2021).

Determination of weight of each formulation:

The weight uniformity of buccal films is a crucial parameter that reflects consistency in the manufacturing process and ensures uniform drug content and dosage accuracy. Variations in weight can directly influence the drug release profile, mechanical properties, and patient compliance. Uniform weight distribution across buccal films is typically achieved by maintaining consistent thickness during the casting or printing process. Factors such as polymer type, viscosity of the film-forming solution, drying conditions, and the precision of the casting equipment significantly impact weight uniformity. Deviations in weight could indicate issues like uneven spreading of the solution, air bubble entrapment, or improper drying, which may lead to suboptimal drug delivery. Hence, weight observation and standardization are critical quality control measures to ensure reproducibility, therapeutic efficacy, and safety of buccal films in clinical applications (Reddy and Murthy., 2018).

Table: Weight of each film, with different polymer:

SELETED FORMULATIONS	BATCHES MADE						AVERAGE WEIGHT (MG)
	B1	**B2**	**B3**	**B4**	**B5**	**B6**	
CHITOSAN (F3)	109	105.7	107	105	106	107.5	106.7
GUAR GUM (F6)	25	27	26	28	26	25	26.16
SODIUM ALGINATE (F9)	34.6	36	36	34	35	34	34.9

Results of weight variation test:

The weight variation test is a critical quality control parameter for buccal films, ensuring uniformity in dosage and reproducibility during production. This test assesses the consistency in the weight of individual film samples within a batch, which directly correlates with the uniformity of drug content and overall product quality. Variations in weight can arise from factors such as inconsistent spreading of the film-forming solution, fluctuations in polymer concentration, drying conditions, or differences in film thickness during the manufacturing process.

To perform the test, multiple films are weighed individually, and the mean weight is calculated. The deviation of individual weights from the mean is evaluated to determine compliance with acceptable limits, as defined by regulatory guidelines. Excessive weight variation may lead to issues such as uneven drug distribution, altered dissolution profiles, or inconsistent therapeutic outcomes. Thus, achieving minimal weight variation is essential for ensuring the safety, efficacy, and reliability of buccal films, particularly in formulations designed for precise dosing and controlled drug delivery (Sofi et al., 2020).

Table: Weight variation of each polymer:

SELETED FORMULATIONS	BATCHES MADE						AVERAGE WEIGHT VARIATION (mg)
	B1	B2	B3	B4	B5	B6	
CHITOSAN (F3)	2.1	0.94	0.28	1.59	0.65	0.75	1.05
GUAR GUM (F6)	4.43	3.21	0.61	7.03	0.61	4.43	3.38
SODIUM ALGINATE (F9)	0.86	3.15	3.15	2.57	0.28	2.57	2.09

Percentage elongation: The percentage elongation of buccal films reflects their flexibility and ability to withstand stretching without breaking. It is particularly important for ensuring that the films can adapt to the dynamic movements of the buccal mucosa, such as during speech and mastication. High percentage elongation indicates better flexibility, which is essential for user comfort and durability during application. This property is influenced by the composition of the film, including the type and concentration of polymers and plasticizers used. Excessive stiffness or brittleness, indicated by low elongation, can lead to cracking or failure during handling and use, whereas excessive elongation may compromise structural integrity. Thus, optimizing the percentage elongation is vital to achieving a balance between flexibility and mechanical strength for effective and reliable buccal drug delivery systems. The results are expressed in the following table (Upreti and Kumar., 2014).

Table 10: Observation table for percent elongation

Oral Dissolving film	Original length (cm)	Final Length (cm)	Change in Length (Final Length -Initial length) (cm)	%Elongation
Chitosan ODF (F3)	2	2.72	0.72	36%
Guar gum ODF (F6)	2	2.68	0.68	34%
Sodium Alginate ODF (F9)	2	2.66	0.66	33%

Moisture Loss: Moisture loss in buccal films is an important parameter that influences their stability, mechanical properties, and drug release profile. Excessive moisture loss can lead to brittleness, cracking, and reduced flexibility of the films, compromising their ability to adhere to the buccal mucosa and deliver the drug effectively. On the other hand, inadequate moisture loss may result in films that are too soft or sticky, which could affect handling and patient comfort. Moisture loss is influenced by the composition of the film, including the type and proportion of hydrophilic and hydrophobic polymers, as well as the environmental conditions such as temperature and humidity during storage. Maintaining an optimal balance of moisture content is crucial for ensuring the long-term performance, integrity, and usability of buccal films in drug delivery systems (Verma et al., 2021).

Table 13: Observation table for Percent moisture loss

Oral dissolving film	Initial weight(mg)	Final weight(mg)	Change in weight(mg)	Percent moisture loss (%)
Chitosan (F3)	109	107.4	1.6	1.5
Guar gum (F6)	25	24.17	0.84	3.32
Sodium alginate (F9)	34.6	33.8	0.8	2.31

Disintegration test: The disintegration test of buccal films is a key evaluation parameter that measures the time required for the film to break down into smaller fragments or dissolve completely when in contact with a moist environment, such as saliva. This test is crucial for assessing the film's ability to release the drug effectively at the site of application. Factors such as polymer composition, film thickness, and the presence of plasticizers or other excipients significantly influence disintegration time. Films designed for fast drug release typically disintegrate quickly to allow rapid onset of action, while films intended for prolonged drug release are formulated to disintegrate more slowly. The test is often performed in simulated buccal conditions to ensure that the disintegration behavior mimics in vivo performance. An optimal disintegration time is essential to balance drug release kinetics, patient compliance, and therapeutic efficacy in buccal drug delivery systems (Sharma et al., 2016).

Table 11: Observation table for disintegration test

Formulation no	F3	F6	F9
Disintegration time	14s	16s	20s

The disintegration time of all the batches were within limits as per the official compendias.

CONCLUSION AND SUMMARY

The research article on the formulation and evaluation of oral dissolving films utilizing guar gum, chitosan, and sodium alginate as polymers in various concentrations through solvent casting method provides a comprehensive exploration into the development of an efficient, patient-friendly drug delivery system. This study aimed to harness the unique properties of these biopolymers to create films that dissolve rapidly in the oral cavity, offering an alternative to conventional oral dosage forms, particularly beneficial for individuals with swallowing difficulties.

Key findings from the study highlight that the choice of polymer and its concentration significantly influences the physical and mechanical properties of the oral dissolving films. Guar gum, known for its excellent film-forming and biocompatible properties, contributed to the flexibility and strength of the films. Chitosan, recognized for its mucoadhesive characteristics, enhanced the film's ability to adhere to the mucosal surface, potentially improving drug bioavailability. Sodium alginate, with its capacity to form gels in the presence of calcium ions, played a crucial role in modulating the disintegration time and dissolution rate of the films.

The evaluation of the films revealed that formulations with optimized concentrations of these polymers exhibited superior qualities in terms of tensile strength, elasticity, dissolution time, and uniformity of drug release. The study demonstrated that films with a balanced guar gum, chitosan, and sodium alginate as polymers not only met the desired criteria for rapid disintegration and dissolution but also showed promising potential in improving the palatability and overall patient acceptance of the dosage form.

Furthermore, the research underscored the importance of a systematic formulation approach and thorough evaluation in the development of oral dissolving films. Solvent casting is a common formulation approach for preparing oral dissolving films (ODFs). It involves dissolving a polymer matrix in a suitable solvent to form a homogeneous solution, which may include flavourings and other additives. The solution is then cast onto a flat surface and allowed to dry, resulting in a thin film. After drying, the film is peeled off and cut into individual doses. ODFs offer rapid disintegration in the mouth without water, making them convenient for patients with swallowing difficulties. Solvent casting enables precise control over film characteristics and drug delivery properties, making it a versatile method for ODF production.

In conclusion, this study provides valuable insights into the formulation and evaluation of oral dissolving films using guar gum, chitosan, and sodium alginate as polymers. The findings suggest that these biopolymers, in carefully calibrated concentrations, offer a promising avenue for creating effective, patient-centric drug delivery systems. Future research could focus on exploring the clinical implications of these formulations, assessing their stability, safety, and efficacy in delivering various therapeutic agents. This work lays a solid foundation for advancing oral dissolving film technology, potentially enhancing medication adherence and providing a more agreeable treatment option for patients across diverse populations.

REFERENCES:

1. Chaturvedi, A., P. Srivastava, et al. (2011). "Fast dissolving films: a review." Curr Drug Deliv 8(4): 373-80.
2. Guo, X.; Cun, D.; Wan, F.; Bera, H.; Song, Q.; Tian, X.; Chen, Y.; Rantanen, J.; Yang, M. Comparative assessment of in vitro/in vivo performances of orodispersible electrospun and casting films containing rizatriptan benzoate. *Eur. J. Pharm. Biopharm.* **2020**, *154*, 283–289.
3. Gupta, A., A. Mishra, et al. (2010). "Recent trends of fast dissolving tablet-an overview of formulation technology." 1(1): 1-10.
4. Kumar, R. S., T. N. S. J. J. o. D. D. Yagnesh, et al. (2019). "Oral dissolving films: an effective tool for fast therapeutic action." 9(1-s): 492-500.
5. Kushwaha, V., J. Akhtar, et al. (2015). "A review on fast dissolving formulation technologies." 4(7): 574-85.
6. Maciel, V.B.; Remedio, L.N.; Yoshida, C.M.; Carvalho, R.A. Carboxymethyl cellulose-based orally disintegrating films enriched with natural plant extract for oral iron delivery. *J. Drug Deliv. Sci. Technol.* **2021**, *66*, 102852.
7. Morales JO, McConville JT. Manufacture and characterization of mucoadhesive buccal films. Eur. J. Pharm. Biopharm. 2011;77:187–199.10.1016/j.ejpb.2010.11.023
8. Nagaraju, T., R. Gowthami, et al. (2013). "Comprehensive review on oral disintegrating films." Curr Drug Deliv 10(1): 96-108.
9. Pacheco, M. S., D. Barbieri, et al. (2021). "A review on orally disintegrating films (ODFs) made from natural polymers such as pullulan, maltodextrin, starch, and others." Int J Biol Macromol 178: 504-513.
10. Patel, P., B. G. Prajapati, et al. (2023). "Mouth dissolving film as a potential dosage form for paediatric usage." 11(2): 133-141.
11. Pattewar, S. V., S. B. Kasture, et al. (2016). "A new self microemulsifying mouth dissolving film." 50: S191-S199.
12. Pawar, R., R. Sharma, et al. (2019). "Formulation and evaluation of mouth dissolving film of prochlorperazine maleate." 9(6): 110-115.

13. Reddy, P.S.; Murthy, K.R. Formulation and evaluation of oral fast dissolving films of poorly soluble drug ezetimibe using transcutol Hp. *Indian J. Pharm. Educ. Res.* **2018**, *52*, 398–407.

14. Sofi, H.S.; Abdal-Hay, A.; Ivanovski, S.; Zhang, Y.S.; Sheikh, F.A. Electrospun nanofibers for the delivery of active drugs through nasal, oral and vaginal mucosa: Current status and future perspectives. *Mater. Sci. Eng. C Mater. Biol. Appl.* **2020**, *111*, 110756

15. Upreti, K., L. Kumar, et al. (2014). "Formulation and evaluation of mouth dissolving films of paracetamol." 6(5): 200-202.

16. Verma, D. and S. K. J. I. J. o. B. M. Sharma (2021). "Recent advances in guar gum based drug delivery systems and their administrative routes." 181: 653-671.